

**REMARKS/ARGUMENTS**

Upon entry of the amendments, claims 1-4, 10-14, 16, 18, 19, 25, 26, 38, 39 and 42-44 will be pending in the application. Claims 14, 18-20 and 26 have been rejected. Claim 1 has been amended to more clearly define the present invention. Support for this amendment can be found in the specification, e.g., page 7, lines 2-7; page 8, lines 6-8; Figure 1A-1I; page 9, lines 14-21; page 10, line 14 – page 11, line 4; page 24, lines 27-29; page 14, line 15 – page 15, line 13; page 38, line 22 – page 39, line 14; page 60, line 24 – page 63, line 7; page 8, line 12-14; Table 1 and Figure 4. No new matter is added.

**SPECIFICATION OBJECTIONS**

The Examiner has objected to the specification for reciting the incorrect address for the American Type Culture Collection (ATCC). Applicants thank the Examiner for pointing out this oversight and, as suggested, have amended the specification to recite the current address for the ATCC. Thus, this objection is moot and should be withdrawn.

**THE 35 U.S.C. §112, SECOND PARAGRAPH REJECTIONS**

The Examiner has rejected claims 1-4, 10-14, 16, 18, 19, 25, 26, 38, 39 and 42-44 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner states that claim 1 is vague and indefinite for reciting “a polynucleotide, when administered in an immunogenically-effective amount to a mammal, induces an immune response in said mammal against said strain of *Chlamydia*” because it is unclear to what part or antigen of the chlamydial strain the immune response is directed to: polynucleotide, polypeptide, an intracellular antigen, or an extracellular antigen. The Examiner further states that it is unclear how it would be effective against “said strain of *Chlamydia*” (Office Action at page 4).

Applicants traverse. Claim 1 has been amended to recite “against infection by said strain of *Chlamydia*.” Support for this amendment can be found in the specification, e.g., page 60, line 24 – page 63, line 7; page 8, line 12-14; Table 1 and Figure 4. Applicants submit that amended claim 1 and claims 2-4, 10-14, 16, 18, 19, 25, 26, 38, 39 and 42-44 which depend, directly or indirectly, from claim 1 and necessarily contain all the limitations of claim 1, point out and distinctly define the metes and bounds of the subject matter that Applicants regard as

their invention. Therefore, Applicants respectfully request reconsideration and withdrawal of the present rejection.

**THE 35 U.S.C. §112, FIRST PARAGRAPH REJECTIONS**

The Examiner has rejected claims 1-4, 10-14, 16, 18, 19, 25, 26, 38, 39 and 42-44 under 35 U.S.C. §112, first paragraph, asserting that there appears to be no descriptive support in the specification for the limitation “a polynucleotide that has a complementary sequence to SEQ ID NO:1” (Office Action at page 4)

Applicants traverse. Claim 1 has been amended to delete “that has a complementary sequence to.” Claim 1, as amended herein, is drawn to an isolated polynucleotide from a strain of *Chlamydia* selected from the group consisting of a polynucleotide comprising the nucleotide sequence of SEQ ID NO:1 (support can be found in the specification at page 7, lines 2-7; page 8, lines 6-8; and Figure 1A-1I); a polynucleotide at least 95% homologous to the nucleotide sequence of SEQ ID NO:1 (support can be found in the specification at page 9, lines 14-21; page 10, line 14 – page 11, line 4; and page 24, lines 27-29); and a polynucleotide which hybridizes under stringent hybridizing conditions of 6xSSC containing 50% formamide at 42°C with a polynucleotide comprising the nucleotide sequence of SEQ ID NO:1(support can be found in the specification at page 14, line 15 – page 15, line 13; and page 38, line 22 – page 39, line 14), wherein administration of said isolated polynucleotide, in an immunogenically-effective amount to a mammal, induces a immune response in said mammal against infection by said strain of *Chlamydia* (support can be found in the specification at page 60, line 24 – page 63, line 7; page 8, line 12-14; Table 1 and Figure 4).

Applicants submit that amended claim 1 and claims 2-4, 10-14, 16, 18, 19, 25, 26, 38, 39 and 42-44 which depend, directly or indirectly, from claim 1 and necessarily contain all the limitations of claim 1, meet the written description provision of 35 U.S.C. §112, first paragraph. Therefore, Applicants respectfully request reconsideration and withdrawal of the present rejection.

**THE 35 U.S.C. §102 REJECTIONS**

The Examiner has rejected claims 1-4, 10-14, 16, 18, 19, 25, 26, 38, 39 and 42 under 35 U.S.C. §102(e) as being anticipated by WO 97/58953 to Knudsen et al. (“Knudsen”). The Examiner states that Knudsen discloses a DNA sequence which is more than 90% identical to

SEQ ID NO:1 and also discloses expression vectors, cells and kits for using/expressing the same. Further, the Examiner states that the DNA of Knudsen is expected to hybridize under the recited hybridizing conditions with the polynucleotide recited in part (b) of claim 1 (Office Action at page 5).

Applicants traverse. As discussed *supra*, claim 1 as amended herein, is drawn to an isolated polynucleotide from a strain of *Chlamydia* selected from the group consisting of a polynucleotide comprising the nucleotide sequence of SEQ ID NO:1; a polynucleotide at least 95% homologous to the nucleotide sequence of SEQ ID NO:1; and a polynucleotide which hybridizes under stringent hybridizing conditions of 6xSSC containing 50% formamide at 42°C with a polynucleotide comprising the nucleotide sequence of SEQ ID NO:1, wherein administration of said isolated polynucleotide, in an immunogenically-effective amount to a mammal, induces a immune response in said mammal against infection by said strain of *Chlamydia*.

Knudsen does not teach or suggest a polynucleotide comprising the nucleotide sequence of SEQ ID NO:1 as recited in part (a) as the DNA disclosed in Knudsen only shows 92.5% identity to SEQ ID NO:1. Knudsen does not teach or suggest a polynucleotide at least 95% homologous to the nucleotide sequence of SEQ ID NO:1 as recited in part (b) as, again, the DNA disclosed in Knudsen only shows 92.5% identity to SEQ ID NO:1. Finally, Knudsen does not teach or suggest a polynucleotide which hybridizes under stringent hybridizing conditions of 6xSSC containing 50% formamide at 42°C with a polynucleotide comprising the nucleotide sequence of SEQ ID NO:1 as recited in part (c), in fact Knudsen does not teach any hybridization sequences or hybridization conditions.

Thus, because Knudsen does not teach or suggest all of the limitations of the claimed invention, Applicants assert that claim 1, as amended herein (and 2-4, 10-14, 16, 18, 19, 25, 26, 38, 39 and 42, which depend from claim 1) are not anticipated by Knudsen. Therefore, Applicants respectfully request reconsideration and withdrawal of the present rejection.

### THE 35 U.S.C. §103 REJECTIONS

The Examiner has rejected claims 42-44 under 35 U.S.C. §103(a) as being unpatentable over Knudsen in view of U.S. Patent No. 6,403,101 to Murdin et al. (“Murdin”). The Examiner states that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the adenoviral vector or *Salmonella* vector of Murdin to express

the polynucleotide of Knudsen to produce the vaccine vector of the instant invention, with a reasonable expectation of success (Office Action at page 6).

Applicants traverse. Obviousness requires that there be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant. (*In re Kotzab*, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000)). Additionally, all the claimed limitations must be taught or suggested by the prior art. (*In re Royka*, 180 U.S.P.Q. 580 (CCPA 1974)). Applicants submit neither Knudsen nor Murdin, alone or in combination teach or suggest the invention recited in the claims as amended.

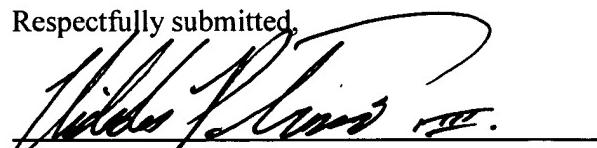
As discussed above, Knudsen does not teach or suggest all of the limitations of claim 1 as amended (and 2-4, 10-14, 16, 18, 19, 25, 26, 38, 39 and 42-44, which depend from claim 1). Murdin does not cure the fatal deficiencies of Knudsen. As described by the Examiner, Murdin merely teaches that chlamydial polynucleotides can be recombinantly expressed in live adenoviral or alphaviral vector, *Shigella* or *Salmonella* vectors.

For the reasons set forth above, the ordinarily skilled artisan would not and could not combine Knudsen or Murdin to achieve the claimed invention. Therefore, Applicants respectfully request reconsideration and withdrawal of the present rejection.

### **CONCLUSION**

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



---

Ivor R. Elrifi, Reg. No. 39,529  
Nicholas P. Triano III, Reg. No. 36,397  
Attorney for Applicants  
c/o MINTZ, LEVIN  
**Customer Number 30623**  
Tel: (617) 542-6000  
Fax: (617) 542-2241

Dated: November 13, 2003